IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **ALL PLAINTIFFS LISTED IN PLAINTIFFS' MOTION**	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE OPINIONS AND TESTIMONY OF JOYE K. LOWMAN, M.D., M.P.H.

At trial, Defendants Johnson & Johnson and Ethicon, Inc. (Ethicon) intend to present the testimony of Joye Lowman, M.D., M.P.H.—a urogynecologist with extensive experience in surgical repair of female pelvic floor dysfunction—to testify in part regarding the safety of Prolift. Plaintiffs do not challenge the qualifications of Dr. Lowman, nor do they claim that her testimony is unreliable. Instead, they claim that Dr. Lowman's testimony regarding the safety of Prolift does not fit the facts of these cases—*i.e.*, that her testimony is not relevant. To do so, however, Plaintiffs mischaracterize Dr. Lowman's opinions and the factual bases for those opinions.

Plaintiffs also complain about a factual anecdote contained in Dr. Lowman's report that highlights her opinion that an alternative procedure for prolapse repair is not safer than Prolift. Plaintiffs assume incorrectly that this inherently factual testimony should be prohibited according to the admissibility standards for scientific evidence stated in *Daubert v. Merrell Dow Pharms. Inc.*, 509 U.S. 579 (1993). Further, while it would be premature to rule on the

admissibility of this evidence at this time, Dr. Lowman's anecdote provides direct support for her testimony on an issue that Plaintiffs have made relevant to these cases.

For these reasons, which are set forth in more detail below, this Court should deny Plaintiffs' motion.

ARGUMENT

I. Dr. Lowman Can Properly Testify To The Safety of Prolift.

Dr. Lowman—an unquestioned expert on surgical repair of female pelvic floor dysfunction—has opined generally that Prolift is safe for use in prolapse repair. In a one-page argument, Plaintiffs attempt to summarize Dr. Lowman's detailed report on the safety of Prolift as follows: "[Dr. Lowman] reasoned that since Prolift is a reasonable option for certain high-risk patients the product as sold and marketed by Ethicon is reasonably safe for its intended use and not defective." Pls.' Mem. (Dkt. 2067) at 3-4. Because they believe that Prolift was marketed to all women, regardless of whether or not they were high risk, Plaintiffs argue that Dr. Lowman's opinions do not fit the facts of these cases. *Id.* at 4. Dr. Lowman, however, did not limit her opinion regarding the safety of Prolift to high-risk patients. Thus, the whole premise of Plaintiffs' *Daubert* argument fails at the outset.

Dr. Lowman made clear in her report that Prolift was a safe treatment option for all patients, not just high-risk patients: "Overall, the evidence supports the use of vaginal mesh augmentation to decrease recurrence risk in patients, particularly those in whom abdominal or lengthy surgery may be unnecessarily risky (obesity, multiple prior abdominal surgeries, medical comorbidities, advanced age, etc.)." Ex. B to Pls.' Mot. (Dkt. 2061-2), Lowman Report at 20. While she does discuss the safety of Prolift in high-risk patients, Dr. Lowman makes very clear that her opinions about safety are not limited to just these patients: "additional studies on Prolift

have been published since these statements where *Prolift was shown to be safe and effective in primary and recurrent prolapse repair*." *Id.* at 15-16 (emphasis added).

In their motion, Plaintiffs focus narrowly on Dr. Lowman's description of statements by four medical societies in 2011 that "there is a role for vaginal mesh augmentation in patients at high risk of recurrence." *Id.* at 14. Plaintiffs imply that it is Dr. Lowman's opinion that mesh products "should be reserved for high-risk individuals," when in fact, Dr. Lowman quotes this language to show that these medical societies' opinions are "consistent" with her opinions in these cases. *Id*. at 15. More egregiously, Plaintiffs ignore Dr. Lowman's discussion of the utility of Prolift in *all* patients, *supra*, that followed in the very next paragraph. *Id*. As described here, the whole premise of Plaintiffs' "fit" argument fails. Thus, this Court should deny their motion to limit the opinions of Dr. Lowman.

Even if Dr. Lowman's general opinion regarding the safety of Prolift was limited to its use in high-risk patients, Plaintiffs' argument that this opinion does not fit these cases still fails. At a minimum, testimony regarding Prolift's safety in high-risk patients would be relevant to cases involving patients who fall into this high risk category. Plaintiffs do not allege—much less explain—why they do not fit into this category of patients. In fact, in the expert report attached to their motion, Dr. Lowman explains in great detail why Plaintiff Patricia Hammons was a high-risk patient and why Prolift was an appropriate choice for her prolapse repair. Ex. B to Pls.' Mot. (Dkt. 2061-2), Lowman Report at 24-30. Thus, Dr. Lowman's testimony is relevant to Plaintiffs' claims.

II. Dr. Lowman's Testimony On Alternative Procedures Is Relevant And Admissible.

In her report, and as part of her opinions regarding the safety of Prolift, Dr. Lowman describes the risk of serious complications from an alternative prolapse repair procedure that is performed laparoscopically, sharing an anecdote about an adverse outcome from a colleague's use of the alternative procedure. At the outset, Dr. Lowman's anecdote is based on her personal knowledge and clinical experience as a urogynecologist, which this Court has recognized is sufficient to satisfy *Daubert*. *See Hovey v. Cook Inc.*, No. 2:13-cv-18900, 2015 WL 1405565, at *13 (S.D.W. Va. Mar. 26, 2015) (recognizing that "'[i]n certain fields, experience is the predominant, if not sole, basis for a great deal of reliable expert testimony'" and finding that urology expert's clinical experience implanting mesh was sufficient basis for his opinions regarding the potential of mesh to cause injuries); *see also Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 727 (S.D.W. Va. 2014) (finding an expert "drawing on her own clinical experience is a sufficiently reliable method of forming" an expert opinion).

Alternatively, Plaintiffs seek to bar this testimony on hearsay, relevance, and unfair prejudice grounds. As Plaintiffs themselves concede, however, expert opinions need not be based on admissible evidence; instead, experts can rely on otherwise inadmissible evidence if "experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject." Fed. R. Evid. 703. As noted above, this Court has previously recognized that clinical experience is a reliable basis upon which to reach an expert opinion on surgical risks. *Huskey*, 29 F. Supp. 3d. at 727; *Hovey,* 2015 WL 1405565, at *13. As such, Dr. Lowman's anecdote need not be admissible to form the basis of her opinions.

Further, at a minimum Dr. Lowman can disclose this anecdote to the jury because its probative value substantially outweighs its prejudicial effect. *See* Fed. R. Evid. 703. Indeed, this

testimony is relevant as it is Plaintiffs who have challenged the safety of Prolift and compared it to alternative procedures for performing prolapse repairs. While Defendants do not concede that evidence of alternative procedures (as opposed to alternative designs) is relevant to design defect claims, if this evidence is admissible, then Dr. Lowman's testimony that those procedures are not "safer" than prolapse repair using Prolift is relevant. *See, e.g., Mullins v. Ethicon, Inc.*, 117 F. Supp. 3d 810, 816 n.6 (S.D.W. Va. 2015) (surveying state law design-defect claims and recognizing that "risk-benefit" test requires proof of a "substitute product" that would "not be as unsafe").

Other than to negate their claim regarding the safety of an alternative procedure for prolapse repair—which is an entirely legitimate purpose—Plaintiffs cannot demonstrate any prejudice they would suffer from Dr. Lowman's testimony. On the contrary, Plaintiffs themselves will attempt to prove the defective nature of Prolift through analogous testimony of the complications they have suffered from mesh implantation. Thus, this Court should deny Plaintiffs' motion on this issue.

In any event, neither Ethicon nor this Court can predict how Plaintiffs or their experts will present their design-defect case to the jury, and thus Ethicon does not concede that Dr. Lowman's anecdote would be otherwise admissible. It is not difficult to imagine a circumstance when Dr. Lowman's anecdote would be relevant and admissible—for example, to contradict testimony from Plaintiffs' experts that alternative procedures for prolapse repair came without serious risks. As such, any decision on whether this anecdote is admissible—in whole or in part—is more properly made at the time of trial.

CONCLUSION

For the foregoing reasons, this Court should deny Plaintiffs' Motion to Exclude Opinions and Testimony of Joye K. Lowman, M.D., M.P.H.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on May 9, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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